

EXHIBIT M



Occupational Medicine, Epidemiology and Prevention

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JACQUELINE MOLINE, MD, MSc STATEMENT ON EPA'S DRAFT RISK EVALUATION OF ASBESTOS

My name is Dr. Jacqueline Moline, and I am a board certified physician, specializing in Occupational and Environmental Medicine. I am currently the Chairperson of the Department of Occupational Medicine, Epidemiology and Prevention at the Donald & Barbara Zucker School of Medicine at Hofstra University/Northwell Health. I am the Director of the Northwell Health Queens World Trade Center Health Program and the Director of the New York State funded Occupational and Environmental Medicine of Long Island Clinical Center.

My specialty, occupational and environmental medicine, deals with the impact of exposures on the health of individuals. It is part of Preventive Medicine, since we know that individuals without these exposures would likely not be afflicted with the conditions they later develop. After I completed my Internal Medicine residency at Yale University, I began my training in Occupational and Environmental Medicine at the Icahn School of Medicine at Mount Sinai, where I had the opportunity to study with some of the leading experts in the field of asbestos-related disease. Throughout my career, I have dedicated myself to studying the prevention and treatment of exposure-related illnesses, including diseases caused by asbestos. Asbestos is one of the most prolific occupational hazards in our country and continues to kill nearly 40,000 people each year in the United States alone. While many countries have banned the use of asbestos, it is currently still permitted to be imported and used in the United States.

OVERVIEW STATEMENT

I have reviewed the recent draft risk evaluation on asbestos released by the Environmental Protection Agency (EPA). While I agree with EPA's findings that nearly all current uses of asbestos and asbestos-containing products present unreasonable risks, I am concerned that the draft has serious omissions and does not reflect the full magnitude of the dangers of asbestos exposure.

I want to focus my comments on one significant source of asbestos exposure and risk that the draft fails to address -- the presence of asbestos contamination in talc used in industrial and consumer products. There is extensive test data documenting the presence of asbestos in certain grades of talc and studies show that exposure to these talc types is linked to asbestos-related diseases. While the presence of asbestos in talc-based cosmetics like baby powder and makeup has recently received

considerable attention from agencies and scientists, these products are regulated by FDA. There has been less focus on asbestos exposure from talc-based products and industrial operations within the purview of the Toxic Substances Control Act (TSCA), which is the basis for the draft EPA risk evaluation.

As discussed below, I believe these talc-related risks need more attention and should be included in the EPA evaluation. Their omission from the current draft also highlights two other serious gaps in the evaluation. Asbestos in talc is linked to ovarian cancer yet EPA has excluded all asbestos-related malignancies from the evaluation except for lung cancer and mesothelioma. In addition, the asbestos found in talc is a mixture of fiber types but EPA only examines risks from chrysotile in the mistaken belief that this is the only fiber in current products. If asbestos in talc is added to the draft evaluation, EPA would need to address both of these limitations so that talc-related risks could be fully assessed.

WHAT IS TALC

Talc is a mineral mined from underground deposits. It is comprised of silicon, magnesium, and oxygen. Talc is the softest mineral known to man and that property offers advantages in a wide range of consumer and industrial products. Talc's most useful characteristic is its ability to absorb moisture, including both water-based and oil-based human moisture and perspiration. Crushing raw talc transforms it to a powder. Talc is mined domestically and imported from several countries. The leading talc-producing countries in 2018 were China, India, Brazil, the United States, South Korea, France, Japan, and Finland.¹ Numerous other countries are minor producers of talc. In the US, talc is found in the eastern Appalachian and Piedmont regions from New England to Alabama. Important deposits are also located in California, Montana, Nevada, Texas and Washington.

Not every talc deposit contains asbestos. However, talc deposits have been identified in mineral formations that include, or are located near, asbestos deposits. Because of this co-location, asbestos-containing talc has been identified and documented by geologists for years. These asbestos containing deposits can contain tremolite or anthophyllite, both forms of amphibole asbestos, and chrysotile, which is the serpentine form of asbestos. According to the International Agency for Research on Cancer (IARC), "...as late as 1973, some talc products sold in the USA contained detectable levels of chrysotile asbestos, tremolite or anthophyllite (Rohl et al, 1976) and it is possible that they remained on the market in some places in the world for some time after that (Jehan, 1984)."

LINK BETWEEN TALC EXPOSURE AND ASBESTOS-RELATED DISEASE

Health officials long ago noted that New York talc miners were dying from lung scarring, including asbestos bodies in the scarred lung tissues and pathology "similar to [findings] reported in asbestosis."² New York state labor protection officials noted that other writers had attributed talc lung scarring to the fibrous varieties of talc, and observed that, for New York talc miners, "In general, the clinical, [chest X-ray], and pathological findings were similar to those observed in

¹ <https://geology.com/minerals/talc.shtml>

² FW Porro et al., Pneumoconiosis in the Talc Industry. *Am. J. Roent. Radium Therapy* 47: 507-524, 1942. Quote from FW Porro et al., Pathology of Talc Pneumoconiosis with Report of an Autopsy. *North. N. Y. Med. J.* 3: 23-25, 1946.

asbestosis.”³ It was also found that these talc miners had an excessive death rate from cancers of the lung and pleura.⁴

Starting in 2002, there have been published reports of cases of mesothelioma, considered a signal tumor for asbestos exposure, among New York talc miners. An epidemiology report sponsored by R. T. Vanderbilt Company found 2 cases among the 782 white men who had been employed for at least one day at the New York talc mines between 1948-1989.⁵ Meanwhile, independent pathologists reported finding at least 8 confirmed cases of mesothelioma among New York state talc miners and millers as of 1986, and subsequently added 5 additional cases.⁶ Commercial amphibole (amosite and crocidolite) asbestos fibers were virtually absent in the lung tissues of all 10 cases subjected to pathological examination, indicating that other occupational asbestos exposures (e.g., in construction) were not responsible for these mesotheliomas of these workers.

A recent effort by Finkelstein to update Honda et al. (2002) provides further evidence that asbestos-containing talc causes mesothelioma.⁷ Finkelstein's update of Honda, using assumptions that would lead to an underestimate of the risk of mesothelioma (underestimating number of mesotheliomas from the cohort and overestimating number of person years at risk ("PYR")), "found [t]here were at least five new cases of mesothelioma in the cohort and mesothelioma incidence rates were at least five (1.6-11.7) times the rate in the general population." Based on this finding, Finkelstein concluded that "it is prudent, on the balance of probabilities, to conclude that dusts from New York State talc ores are capable of causing mesothelioma in exposed individuals."

There is substantial evidence that talcs from other areas also contain substantial amounts of asbestos (or asbestiform fibers) that can cause mesothelioma. For example, talc from Death Valley, California often contains amphibole asbestos that can cause mesothelioma. Van Gosen identified amphibole asbestos in numerous talcs from the Death Valley mines. Recently, Compton examined white talc ore from the Grantham Mine (source of ore for Sierra Talc and later owned by Johns-Manville Corp.). Using polarized light microscopy (PLM), Compton found "[t]he mineral sample was found to contain 5-15% (by volume) tremolite/actinolite as determined by PLM. The sample contains asbestiform fibers consistent with fibrous tremolite (see Figures 2 and 3) and fibrous talc.” (italics in original).⁸ Tests of other sources of talc have yielded similar results.

ASBESTOS DISEASES AND PERSONAL CARE PRODUCTS

Recently, studies by FDA and others have documented the presence of asbestos in a variety of personal care products and cosmetics.⁹ These include baby powder and a wide range of talc-based

³ M Kleinfeld et al., Talc Pneumoconiosis. *Arch. Ind. Health* 12: 66-72, 1955; M Kleinfeld et al., Talc Pneumoconiosis/A Report of Six Patients with Postmortem Findings. *Arch. Env. Health* 7: 101-115, 1963

⁴ M Kleinfeld et al, Mortality among Talc Miners and Millers in New York State. *Indust. Hyg. Review* 9: 3-12, 1967.

⁵ Y Honda et al., Mortality among Workers at a Talc Mining and Milling Facility. *Ann. Occup. Hyg.* 46: 575-585, 2002).

⁶ MJ Hull et al., Mesothelioma among Workers in Asbestiform Fiber-bearing Talc Mines in New York State. *Ibid.* Suppl. 1, 132-136, 2002

⁷ Finkelstein, Malignant Mesothelioma Incidence Among Talc Miners and Millers in New York State, *Am. J. Ind. Med.* 55(10):863-8 (Oct. 2012).

⁸ Compton, Report of Results: MVAJ 1054 Analysis of Grantham Mine Talc for asbestos, Prepared for: Maune Raichle Hartley French & Mudd, LLC, 70 Washington St., Suite 425 Oakland, CA 94607 (July 8, 2015).

⁹ October 11, 2019 - AMA Analytical Services, Inc. Summary of Asbestos and Talc Analysis - Johnson & Johnson - Baby Powder Lot #22318RB, From: www.fda.gov/media/131989/download

makeup products sold by Claire's and Justice. My recent work has focussed on understanding the relationship between use of these products and elevated levels of mesothelioma and ovarian cancer in the female population.

Many women diagnosed with mesothelioma had no traditional source of asbestos exposure. As a result, their mesotheliomas were considered "idiopathic," or having no known cause. However, there is now evidence that the presence of asbestos in cosmetic talcum powder, more commonly used by women, is likely the cause of many women's mesothelioma, who have no other known asbestos exposure. Years ago, other scientists evaluated lung burdens of women with mesothelioma. They found the types of asbestos commonly found in talcum powder in their lungs. They stated that these asbestos fibers might be related to the use of contaminated cosmetic talc.¹⁰ However, in these papers, there was no information regarding whether these women had been asked about their use of cosmetic talc.

To address this gap, I recently published an article in the Journal of Occupational and Environmental Medicine.¹¹ As Wagner did in 1960 in a case report of 33 individuals with asbestos exposure and mesothelioma¹², my colleagues and I reported on 33 individuals with mesothelioma with no other identifiable source of exposure apart from cosmetic talc. In this case series, we reported in depth on six individuals for whom tissue digestion analysis was performed. This testing, in addition to their history of consistent use of cosmetic talc, identified asbestos and talc fibers in their tissue. In 2020 Emory et al. published a larger case series of 75 additional patients with cosmetic talcum powder exposure and mesothelioma. There are now over 110 cases of mesothelioma reported in the peer-reviewed medical literature identifying mesothelioma among users of cosmetic talc.¹³

In addition to mesothelioma, more and more evidence is coming to light to support the proposition that cosmetic talcum powder is causing some women's ovarian cancer as well. The scientific evidence is clear that asbestos causes ovarian cancer.¹⁴ Recent studies that have looked at perineal talc exposure and ovarian cancer risk have found elevated cancer risk, particularly for the most common type of ovarian cancer: serous carcinoma of the ovary.¹⁵ The authors of these papers do

October 11, 2019 - AMA Analytical Services, Inc. (Supporting Data) INV-106924_LabReview-2.1: AMA Laboratory Report 308006 (56 pages); <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products>

¹⁰ Churg, A. Warnock ML. Asbestos and other ferruginous bodies. Am J Pathol. 1981; 102:447-56; Roggli, Victor, et al. Tremolite and Mesothelioma, Ann Occup Hyg. 2002;46(5):447-53.

¹¹ Moline J, Bevilacqua K, Alexandri M, Gordon RE. Mesothelioma Associated with the Use of Cosmetic Talc. J Occup Environ Med. 2019 Oct 10. doi: 10.1097/JOM.0000000000001723. [Epub ahead of print] PubMed PMID: 31609780.

¹² Wagner JC, Sleggs CA, Marchand P. Diffuse pleural mesothelioma and asbestos exposure in the North Western Cape Province. Occupational and Environmental Medicine. 1960 Oct 1;17(4):260-71.

¹³ Emory TS, Maddox JC, Kradin RL. Authors' response to "malignant mesothelioma following exposure to cosmetic talc: Association, not causation." Am J of Ind Med (2020)DOI:10.1002/ajim.23106; Andrion, Alberto, et al. Malignant Peritoneal Mesothelioma in a 17-Year-Old Boy with Evidence of Previous Exposure to Chrysotile and Tremolite Asbestos, Human Pathology, Volume 25, No. 6 (June 1994). Musti, et al., Exposure to Asbestos and Mesothelioma Risk of Onset of Primary Ovarian, Description of Two Cases, 2009.

¹⁴ Camargo MC, Stayner LT, Straif K, Reina M, Al-Alem U, Demers PA, Landrigan PJ. Occupational exposure to asbestos and ovarian cancer: A meta-analysis. Environmental health perspectives. 2011 Jun 3;119(9):1211-7.

¹⁵ Kadry MT, Farhat N, Karyakina NA, Shilnikova N, Ramoju S, Gravel CA, Krishnan K, Mattison D, Wen SW, Krewski D. Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer.

not differentiate between the risk of talcum powder itself and asbestos as a constituent of the talcum powder.

TALC-BASED CONSUMER PRODUCTS

There is considerable data documenting the presence of amphiboles and other asbestos fibers in talc-based consumer products:

- In 2000, the Seattle Post Intelligencer confirmed that asbestos had been found in crayons.¹⁶
- In 2007, the ADAO's product testing confirmed asbestos in five consumer products, including a child's toy.¹⁷
- In 2015, the Environmental Working Group's (EWG) product testing confirmed four brands of crayons contained asbestos, all of them manufactured in China: Amscan Crayons, Disney Mickey Mouse Clubhouse 10 Jumbo Crayons, Nickelodeon Teenage Mutant Ninja Turtle Crayons, and Saban's Power Rangers Super Megaforce 10 Jumbo Crayons.¹⁸
- In 2018, U.S. Public Interest Research Group tested six kinds of crayons from various brands. Green Playskool crayons were found to contain tremolite asbestos fibers.¹⁹

The presence of asbestos in these products is of particular concern because of their use by children.

INDUSTRIAL TALC USE

According to Geology.com,²⁰ Talc's industrial uses are diverse:

Talc in Plastics

In 2011, about 26% of the talc consumed in the United States was used in the manufacturing of plastics. It is mainly used as a filler. The platy shape of talc particles can increase the stiffness of products such as polypropylene, vinyl, polyethylene, nylon, and polyester. It can also increase the heat resistance of these products and reduce shrinkage. Where the plastic is extruded in the manufacturing process, talc's very low hardness produces less abrasion on equipment than harder mineral fillers.

Talc in Ceramics

In the United States in 2011, about 17% of the talc consumed was used in the manufacturing of ceramics products such as bathroom fixtures, ceramic tile, pottery, and dinnerware. When used as a filler in ceramics, talc can improve the firing characteristics of the greenware and the strength of the finished product.

Talc in Paint

Reproductive toxicology (Elmsford, NY). 2019 Dec. 90:88-101. Berge W, Mundt K, Luu H, Boffetta P. Genital use of talc and risk of ovarian cancer: a meta-analysis. European Journal of Cancer Prevention. 2018 May 1;27(3):248-57.

¹⁶ <https://www.epsc.gov/PageFiles/108033/crayons.pdf>

¹⁷ <https://www.asbestosdiseaseawareness.org/archives/364>

¹⁸ <https://www.ewg.org/enviroblog/2015/07/asbestos-your-children-s-toys>

¹⁹ https://uspig.org/sites/pirg/files/reports/Copy%20of%20USP_Toxics-report_Fall2018_PRINTv1b.pdf

²⁰ <https://geology.com/minerals/talc.shtml>

Most paints are suspensions of mineral particles in a liquid. The liquid portion of the paint facilitates application, but after the liquid evaporates, the mineral particles remain on the wall. Talc is used as an extender and filler in paints. The platy shape of talc particles improves the suspension of solids in the can and helps the liquid paint adhere to a wall without sagging.

Powdered talc is a very bright white color. This makes talc an excellent filler in paint because it simultaneously serves to whiten and brighten the paint. Talc's low hardness is valued because it causes less abrasion damage on spray nozzles and other equipment when paint is applied. In 2011, about 16% of the talc consumed in the United States was used to make paint.

Talc in Paper

Most papers are made from a pulp of organic fibers. This pulp is made from wood, rags, and other organic materials. Finely ground mineral matter is added to the pulp to serve as a filler. When the pulp is rolled into thin sheets, the mineral matter fills spaces between the pulp fibers, resulting in a paper with a much smoother writing surface. Talc as a mineral filler can improve the opacity, brightness, and whiteness of the paper. Talc also can also improve the paper's ability to absorb ink. In 2011, the paper industry consumed about 16% of the talc used in the United States.

Talc in Roofing Materials

Talc is added to the asphaltic materials used to make roofing materials to improve their weather resistance. It is also dusted onto the surface of roll roofing and shingles to prevent sticking. In 2011, about 6% of the talc consumed in the United States was used to manufacture roofing materials.

Other Uses of Talc

Ground talc is used as a lubricant in applications where high temperatures are involved. It is able to survive at temperatures where oil-based lubricants would be destroyed. It has been used in the rubber industry to prevent rubber products from sticking, providing potential exposures to both manufacturers and end users. Talc powder is used as a carrier for insecticides and fungicides. It can easily be blown through a nozzle and readily sticks to the leaves and stems of plants. Its softness reduces wear on application equipment.

These industrial uses likely expose thousands of workers to talc powder by inhalation and dermal contact. The extent to which this talc contains asbestos is not known, but typically industrial-grade talc undergoes less extensive processing than talc used in personal care products and is more likely to contain impurities. Based on my investigation of the link between talc-based baby powder and mesothelioma and ovarian cancer in women, I am concerned that industrial talc exposure is a cause of asbestos-related death and disease.

CONCLUSION

As discussed above, the omission of talc-based consumer and industrial applications from the draft evaluation is a significant gap because of the likelihood that some grades of talc used in these applications are contaminated by asbestos, putting consumers and workers at risk. EPA should include these conditions of use in its risk evaluation. To assure that their risks are assessed fully, it

should also expand the evaluation to include other known health impacts of asbestos like ovarian cancer and address all fiber types, not simply chrysotile.